K071099

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS (AS REQUIRED BY 21 CFR 807.92)

1. GENERAL INFORMATION

MAY 22 2007

Establishment:	IMRIS Inc.
Address:	100-1370 Sony Place Winnipeg, Manitoba Canada R3T 1N5
Registration Number:	3003807210
Contact Person:	Mrs. B. Newis Quality Assurance Representative email: bnewis@imris.com Phone: 1-204-480-7070 ext.7043 Fax: 1-204-480-7071
Date of Summary Preparation:	April 17, 2007
Device Name:	Neuro II-SE Intra-operative Imaging System
Trade Name:	Neuro II-SE
Common Name:	MRDD (Magnetic Resonance Diagnostic Device)
Proprietary name:	Neuro II-SE
Classification name:	System, Nuclear Magnetic Resonance Imaging
Classification:	21 CFR 892.1000
Class:	Class II
Product Code:	LNH (Magnetic Resonance Imaging System)
Performance Standards:	None established under Section 514 of the Food, Drug and Cosmetic Act

2. INDICATIONS FOR USE

The IMRIS Neuro II-SE MRI system is indicated for use for the head and whole body.

3. INTENDED USE OF THE DEVICE

The Neuro II-SE is intended for use as a diagnostic patient imaging device. This device produces tomographic cross-sectional images that:

1. correspond to the distribution of protons exhibiting MR characteristics;
2. depend upon NMR parameters (proton density, flow velocity, spin-lattice relaxation time (T1) and spin-spin relaxation time (T2); and
3. display the soft tissue structure of the head and whole body.

When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

The Neuro II-SE may be used during intra-operative procedures when performed in an intra-operative MRI suite with MR compatible devices such as anesthesia and patient monitoring equipment.

The Neuro II-SE may also be used for imaging in a multi-room suite.

4. DEVICE DESCRIPTION

The Neuro II-SE system is a traditional MRI unit that has been suspended on an overhead rail system to facilitate intra-operative use. The main components of the Neuro II-SE system are the MRI system assembly (including diagnostic RF coils), the magnet mover assembly, the OR Table assembly, Head Fixation Device and the Intra-operative Coil.

5. SAFETY AND EFFECTIVENESS

The Neuro II-SE (OR-DR-OR/OR-MB configurations) have been designed to provide MRI imaging in an intra-operative setting in the same manner as the predicate Neuro II –SE System and predicate Neuro II-S devices. The Neuro II-SE's (OR-DR-OR/OR-MB configurations) intra-operative features, including the Magnet Mover Assembly, OR Patient Table, Intra-operative Coil and Head Fixation Device are substantially equivalent to the same intra-operative features of the predicate Neuro II-SE and predicate Neuro II-S. The Neuro II-SE (OR-DR-OR/OR-MB configurations) does not raise any new safety or effectiveness issues related to the use of a moving MRI system in an intra-operative setting.

The Neuro II-SE's (OR-DR-OR/OR-MB configurations) MRI imaging system's software and hardware are substantially equivalent to the Siemens Magnetom Espree 1.5T MRI System. The Neuro II-SE does not raise any new safety issues related to static magnetic field effects, changing magnetic field effects, RF heating or acoustic noise or effectiveness issues related to specification volume, signal to noise, image uniformity, and geometric distortion, slice profile, thickness and gap, or high contrast spatial resolution.

Laboratory testing has been completed to verify the equivalence to the Siemens Magnetom Espree System and to verify the safe and effective intra-operative operation of the Neuro II-SE (OR-DR-OR/OR-MB configurations).

The Neuro II-SE (OR-DR-OR/OR-MB configurations) Intra-operative Magnetic Resonance Imaging System is substantially equivalent to the Siemens Magnetom Espree; the IMRIS predicate Neuro II-SE and the predicate Neuro II-S imaging systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 2 2 2007

IMRIS, Inc.
c/o Mr. Thomas M. Tsakeris
President
Devices & Diagnostics Consulting Group, Inc.
16809 Briardale Road
ROCKVILLE MD 20855

Re: K071099
Trade/Device Name: Neuro II-SE Intra-operative Magnetic Resonance Imaging System
Regulation Number: 21 CFR §892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: April 16, 2007
Received: April 19, 2007

Dear Mr. Tsakeris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: IMRIS Inc.

Device Name: Neuro II-SE Intra-operative Magnetic Resonance Imaging System

Indications For Use:

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The Neuro II-SE is intended for use as a diagnostic patient imaging device. This device produces tomographic cross-sectional images that:

1. correspond to the distribution of protons exhibiting MR characteristics;
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The Neuro II-SE may also be used in a multi-room suite.

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071099

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)